

DETAILED ACTION

1. The response to the office action filed on June 17, 2011 has been considered and acknowledged.

Status of the Application

2. Currently claims 27-35, 39-43, 45 are pending under examination. Claims 36-38 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in view of the amendment. The instantly amended claim 27 recites new limitations that were not present in the previously examined claim. Now the scope of the claims changed, and accordingly new rejections are applied. In addition amendment of claim 45 changed the scope of the claim. This action is made FINAL necessitated by the amendment.

New Grounds of Rejections necessitated by the Amendment

Claim objections

3. Claim 45 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-32, 35, 39-43, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheiness et al. (US 5,700,636)

Sheiness et al. teach a method of claim 27, 40-42, 45, detecting a microorganism in a culture of eukaryotic cells comprising providing

(a) a microarray which comprises at least one nucleic acid probe representing a gene for eukaryotic cell and at least one nucleic acid probe representing a gene (Bio B gene) of a microorganism (see col. 13, line 8-25);

(b) preparing nucleic acid targets from said culture by means of a primer mixture suitable for amplification of said gene from eukaryotic cell and at least one gene from a microorganism (see col. 13, line 66-67, col. 14, line 1-10, col. 11, line 6-63);

(c) contacting the microarray with the nucleic acid targets (see col.13, line 14-25);

(d) correlating the selective hybridization between the nucleic acid targets and at least one nucleic acid probe representing a gene of the microorganism with the presence of a microorganism (see col. 14, line 24-67, col. 15, line 1-13, col. 39-42, example 6).

With regard to claims 29-32, 43, Sheiness et al. teach that the microorganism belongs to class mollicutes that comprises mycoplasma, ureaplasma and the nucleic acid probe representing a gene of the microorganism and the primer specific for the microorganism comprises nucleic acid sequence of 16S or 23S rRNA gene (see col. 14, line 11-67, col. 15, line 1-30, col. 39-44, example 6-7).

With regard to claim 35, Sheiness et al. teach that the eukaryotic cells are human cells (patient sample) (see col. 11, line 42-63).

With regard to claim 28, 39-41, Sheiness et al. teach comparing the gene expression of eukaryotic cells with the gene expression of non-contaminated eukaryotic cells (see col.21, line 20-41, col. 33, line 30-67, col. 34, line 1-7, col. 39-42, example 6). Accordingly the claims are anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheiness et al. (US 5,700,636) in view of Roblin et al. (US 5,693,467) and Harris et al. (US 6,013,510).

Sheiness et al. teach a method for detecting a microorganism contamination in eukaryotic cells as discussed above in section 4. Although Sheiness et al. teach use of rRNA sequence for selection of probe/primer, Sheiness et al. did not specifically teach primers specific for microorganism comprising SEQ No. 1, 3, 4 or 5 and a primer comprising promoter sequence.

Roblin et al. teach a method for detecting mycoplasma by polymerase chain reaction wherein Roblin et al. teach the use of primers (see col. 5, line 21-67, col. 6, line

1-30) wherein the primers having sequence of SEQ ID No. 1 and 19 of Roblin correspond to instant claimed SEQ ID No. 1 and 3 and the alignment of the sequence is as follows

For SEQ ID No.1

INFORMATION FOR SEQ ID NO: 1:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 20 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
US-08-445-289B-1

Query Match 100.0%; Score 20; DB 2; Length 20;
Best Local Similarity 100.0%;
Matches 20; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 ACACCATGGGAGCTGGTAAT 20
|||||
Db 1 ACACCATGGGAGCTGGTAAT 20

For SEQ ID NO. 3

INFORMATION FOR SEQ ID NO: 19:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 27 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
US-08-445-289B-19

Query Match 100.0%; Score 25; DB 2; Length 27;
Best Local Similarity 92.6%;
Matches 25; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

Qy 1 CTCNTCGACTTNCAGACCCAAGGCAT 27
||| ||||| |||||
Db 1 CTCATCGACTTCCAGACCCAAGGCAT 27

Harris et al. teach a method for detecting mycobacterium spp. using T7 and sp6 promoter primers wherein the primer having sequence of SEQ ID No. 2 of Harris et al. correspond to the sequence as claimed in SEQ ID No. 2 (see col. 15, line 50-53).

For SEQ ID NO. 2

INFORMATION FOR SEQ ID NO: 2:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 20 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
US-08-937-580-2

Query Match 100.0%; Score 20; DB 3; Length 20;
Best Local Similarity 100.0%;
Matches 20; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 TAATACGACTCACTATAGGG 20
|||||||
Db 1 TAATACGACTCACTATAGGG 20

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting a microorganism as taught by Sheiness et al. with the use of primers taught by Roblin et al. for the purpose of developing a simple and efficient method for detecting a microorganism contamination of a culture of eukaryotic cells. Further it would have been obvious to modify the method using a promoter primer for the purpose of cloning and sequencing the target nucleic acids identified by the method. One skilled in the art would have motivated to combine the references because the ordinary artisan would have a reasonable expectation of success that the combination would result in a simple, efficient method for simultaneously detecting multiple target nucleic acids and analyzing the base composition and such a modification of the method would be obvious over the cited prior art.

Response to arguments:

6. With regard to the objection to claim informalities, Applicants' arguments and the amendment were fully considered and the objection is withdrawn in view of the amendment.

7. With regard to the rejection of claims 27-35, 39-41 under 35 USC 112 second paragraph, the arguments and the amendment were fully considered and found persuasive. The rejection is withdrawn in view of the amendment.

8. With regard to the rejection of claims 27-35, 39-41 under 35 USC 102(e) as being anticipated by Happe, the arguments and the amendment were fully considered and found persuasive. The rejection is withdrawn in view of the amendment.

9. With regard to the rejection of claims 27-28, 39-42, 44-45 under 35 USC 102(b) as being anticipated by Lockhart et al., the arguments and the amendment were fully considered and found persuasive. The rejection is withdrawn in view of the amendment.

10. With regard to the rejection of claims 29-35 under 35 USC 103(a) as being unpatentable over Happe in view of Lockhart et al., the arguments and the amendment were fully considered and found persuasive. The rejection is withdrawn in view of the amendment.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637